Five-Year Analysis of the JULIET Trial of Tisagenlecleucel in Patients With Relapsed/Refractory Large B-Cell Lymphoma

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ABSTRACT

We report the 5-year analysis of tisagenlecleucel in 115 infused patients with relapsed/refractory (r/r) large B-cell lymphoma (LBCL) from the single-arm, open-label, multicenter, global, phase II JULIET trial (ClinicalTrials.gov identifier: NCT02445248), with a median follow-up of 74.3 months. The median duration of response (DOR) was not reached; the 60-month, relapse-free probability was 61% among responders. Higher relapse-free probability (DOR >70%) was observed in females and those with less than two baseline International Prognostic Index risk factors or with baseline stage I/II disease. The estimated probability of progression-free survival at 60 months was 28%. The probability of overall survival (OS) at 60 months was 32% for all infused patients and 56% for those achieving complete or partial response. Baseline characteristics associated with achieving a response at any time after infusion included relapsed versus refractory disease, one versus two or more bridging regimens, lactate dehydrogenase level ≤upper limit of normal (ULN) versus >ULN, and C-reactive protein levels <15 mg/L versus >15 mg/L. Baseline characteristics associated with long-term OS included lactate dehydrogenase ≤ULN and C-reactive protein <15 mg/L. No new safety signals or secondary T-cell malignancies were reported. These findings continue to support the curative potential of tisagenlecleucel in a subset of patients with r/r LBCL.

ACCOMPANYING CONTENT

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Data Supplement

Protocol

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INTRODUCTION

Chimeric antigen receptor (CAR)–T cell therapy has revolutionized the treatment of relapsed/refractory (r/r) large B-cell lymphoma (LBCL) with impressive efficacy and manageable toxicity.[1-7] Tisagenlecleucel was approved for adults with r/r LBCL after two or more lines of therapy, based on the JULIET trial.[8] Since the primary analysis,[3] extended follow-up has demonstrated durable responses without new safety signals.[9] We report additional long-term efficacy and safety data for tisagenlecleucel in patients with r/r LBCL after >5 years of follow-up, along with exploratory analyses and long-term CAR-T cell persistence.

METHODS

JULIET (ClinicalTrials.gov identifier: NCT02445248), a single-arm, multicenter, global phase II trial, evaluated tisagenlecleucel in adults with r/r LBCL (excluding primary mediastinal LBCL) who had progressed after two or more previous lines of therapy. Full trial design, eligibility criteria, and primary end points have been previously published[3,9]; a summary can be found in the Data Supplement (online only). Patients were followed for 5 years in JULIET and could then enroll in a long-term follow-up study (PAVO, ClinicalTrials.gov identifier: NCT02445222) for an additional 10 years.

This study was sponsored and designed by Novartis with input from the academic members of the Scientific Steering Committee. The study protocol and all amendments were reviewed by the Independent Ethics Committee or Institutional Review Board for each center. The study was conducted according to the International Council for Harmonisation E6 Guideline for Good Clinical Practice. Written informed consent was obtained from each patient or legal guardian in writing before screening.

Prespecified and exploratory time-to-event analyses of duration of response (DOR), progression-free survival (PFS; time from tisagenlecleucel infusion to first documented disease progression or death), and overall survival (OS) were assessed using the Kaplan-Meier method. Additional details on statistical analyses can be found in the Data Supplement.

RESULTS

Efficacy

Patient baseline demographics and disease characteristics are shown in Table 1. Among 115 infused patients (Data Supplement, Fig S1), as of last patient visit on December 22, 2022 (median follow-up, 74.3 months [range, 58.1-86.6 months]), the overall response rate was 53.0% (61/115); 39.1% (45/115) achieved best overall response (BOR) of complete response (CR). Nineteen patients converted from partial response (PR) to CR; most (78.9%, 15/19) conversions occurred within 6 months of infusion (Data Supplement, Fig S2). Four patients converted to CR after month 6; the latest conversion occurred between 24 and 33 months after infusion (Data Supplement). Among 30 patients still in follow-up at 60 months after infusion, 26 (86.7%) had achieved CR as BOR, and 22 (84.6%, 22/26) remained in CR at 60 months (Data Supplement, Fig S3).

TABLE 1. Baseline Demographics and Disease Characteristics

Characteristic	Patients (N = 115), No. (%)
Age, years	
≥40 to <65	72 (62.6)
≥65	26 (22.6)
Sex	
Male	71 (61.7)
Female	44 (38.3)
Previous response status	
Refractory to last line	63 (54.8)
Relapsed to last line	52 (45.2)
IPI at study entry	
<2 risk factors	31 (27.0)
≥2 risk factors	84 (73.0)
Previous lines of therapy, No.	
≤2	56 (48.7)
>2	59 (51.3)
Stage of disease at baseline	
I/II	27 (23.5)
III/IV	88 (76.5)
Previous HCT therapy	
Yes	56 (48.7)
No	59 (51.3)
Molecular subtype	
GC	63 (54.8)
ABC	49 (42.6)
Other	3 (2.6)
Rearrangements in *MYC/BCL2/BCL6*	
Double/triple hits	20 (17.4)
Other	95 (82.6)

Abbreviations: ABC, activated B cell; GC, germinal center; HCT, hematopoietic cell transplant; IPI, International Prognostic Index.

The median DOR was not reached (Fig 1A); the 60-month event-free probability among responders (n = 61) was 60.5% (95% CI, 46.3% to 72.0%). Among patients in the Main Cohort with BOR of CR (Fig 1B, n = 41), the 57-month event-free probability was 75.7% (95% CI, 58.3% to 86.6%). The median OS was 11.1 months (95% CI, 6.6 to 23.9 months; Fig 1C). The median OS among responders with BOR of CR/PR (n = 61) was 76.5 months (95% CI, 37.8 months to not estimable [NE]; Fig 1D). The estimated 60-month OS probability was 31.7% (95% CI, 23.1% to 40.6%) for all patients and 55.8% (95% CI, 41.9% to 67.7%) for patients with BOR of CR/PR. The median disease-specific survival was 21.1 months (95% CI, 10.1 to NE; Fig 1E). Among all infused patients, the median PFS has not changed since last reported[9] (Data Supplement, Fig S4). The estimated 60-month PFS probability was 28% (95% CI, 19.5% to 37.8%). Univariable and multivariable analyses identified several baseline covariates that were significantly associated with overall response rate and OS (Data Supplement, Fig S5).

Safety

The long-term safety profile of tisagenlecleucel remained acceptable >5 years after infusion, with no unexpected late safety concerns. Among 35 safety-evaluable patients (30.4%) >3 years after infusion, late-onset adverse events (AEs) occurred in 14 patients (14/35, 40.0%); eight (8/35, 22.9%) had any-grade infections and eight (8/35, 22.9%) had grade 3/4 AEs (Data Supplement, Table S1). Ten (10/35, 28.6%) patients experienced any-grade AEs of special interest >3 years after infusion (grade 3, n = 3; grade 4, n = 2; Data Supplement, Table S2). In an updated analysis, 45 (39.1%) patients, including 30 (49.2%) responders, received immunoglobulin therapy (Data Supplement, Table S3).

Among infused patients (N = 115), 76 deaths were reported. Disease progression was the most common cause of death (59/76, 78%); most deaths (73/76, 96%) occurred >30 days after infusion—76% (58/76) occurring <12 months after infusion and 92% (70/76) before 36 months. Causes of late (>3 years) nonrelapse mortality (n = 4) included myelodysplastic syndrome (n = 2), bacterial sepsis (n = 1), and respiratory failure (n = 1).

Fifteen secondary malignancy events (all grades) were reported in 13 patients (11.3%; Data Supplement). No secondary T-cell malignancies were reported. No replication-competent lentivirus (RCL) was detected at any time after infusion; there was no indication that events were CAR-transgene or RCL-mediated transformations.

Baseline Characteristics and Biomarkers Associated With Long-Term Outcomes

Overall, 54-month DOR event-free probabilities were largely consistent among subgroups (Data Supplement, Table S4), as was PFS (Data Supplement, Table S5). Multi- and

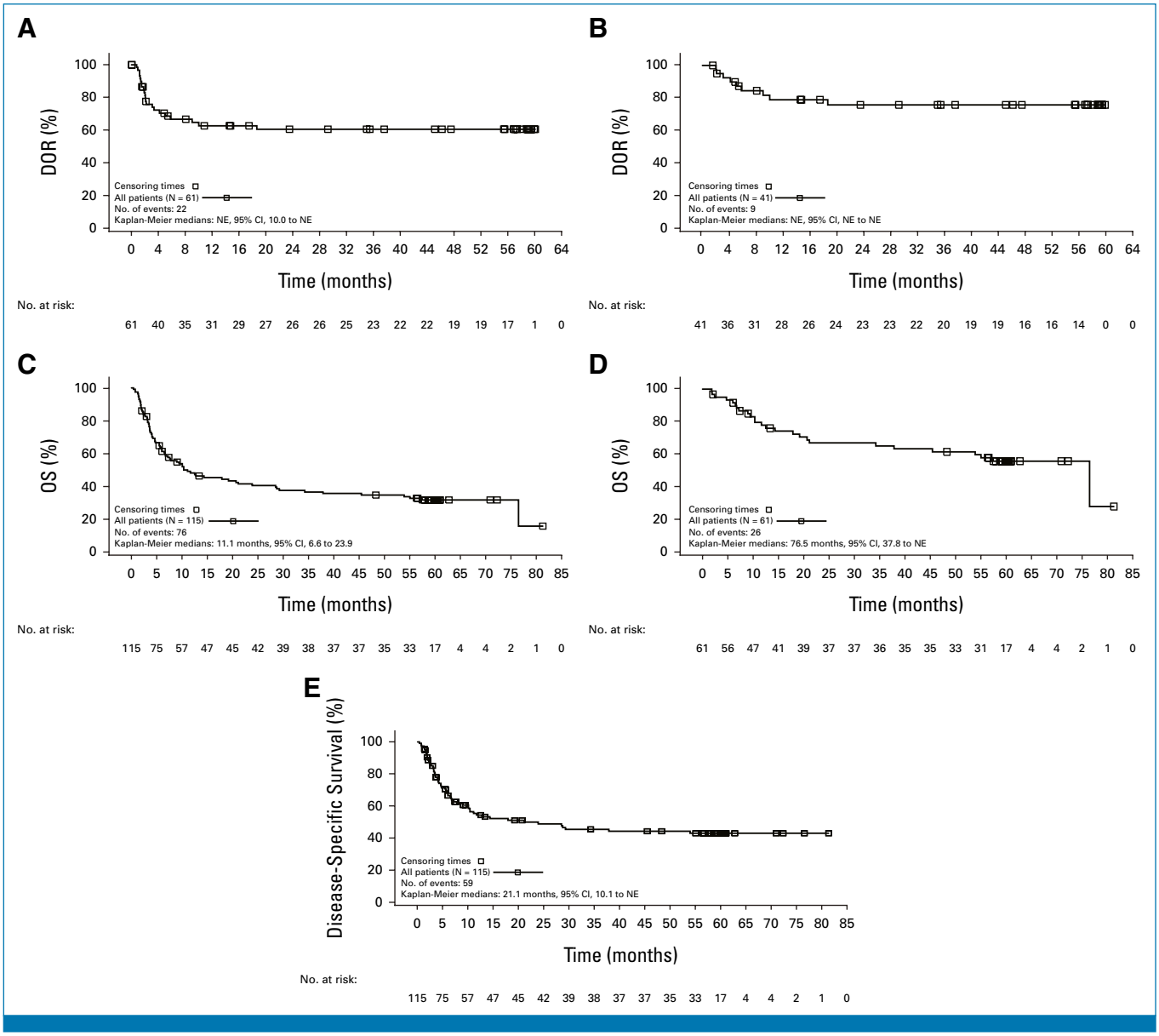

FIG 1. DOR and OS Kaplan-Meier curves. (A) Kaplan-Meier plot of DOR in patients with BICR-assessed response (n = 61). (B) Kaplan-Meier plot of DOR main cohort patients with a BOR of CR (n = 41). (C) Kaplan-Meier plot of OS in the full analysis set (N = 115). (D) Kaplan-Meier plot of OS in patients with a BOR of CR or PR as assessed by the IRC in the full analysis set (n = 61). (E) Disease-specific survival, defined as OS excluding deaths unrelated to disease progression, based on IRC assessment in the full analysis set (N = 115). BICR, blinded independent central review; BOR, best overall response; CR, complete response; DOR, duration of response; IRC, independent review committee; NE, not estimable; OS, overall survival; PR, partial response.

univariable analyses of baseline characteristics can be found in the Data Supplement. Baseline tumor and immune biomarkers significantly affected outcomes after tisagenlecleucel therapy: patients with Myc− tumors (by immunohistochemistry) and higher T-cell infiltration had longer PFS and OS, whereas those with Myc+ tumors, low T-cell infiltration, or higher levels of exhausted T cells had poorer outcomes. Additionally, lower circulating T cells and more exhausted cluster of differentiation 8+ T-cell subsets in peripheral blood before leukapheresis were linked to worse clinical results (Fig 2[10] and Data Supplement, Fig S6).

Long-Term Pharmacokinetics

The last tisagenlecleucel transgene was detected by quantitative polymerase chain reaction in the peripheral blood of responders for up to 1,830 days and in nonresponders for up to 1,480 days (Data Supplement, Fig S7).

DISCUSSION

This 5-year analysis of the JULIET trial demonstrates that tisagenlecleucel induced durable remissions in a substantive proportion of patients with heavily pretreated r/r LBCL. Most

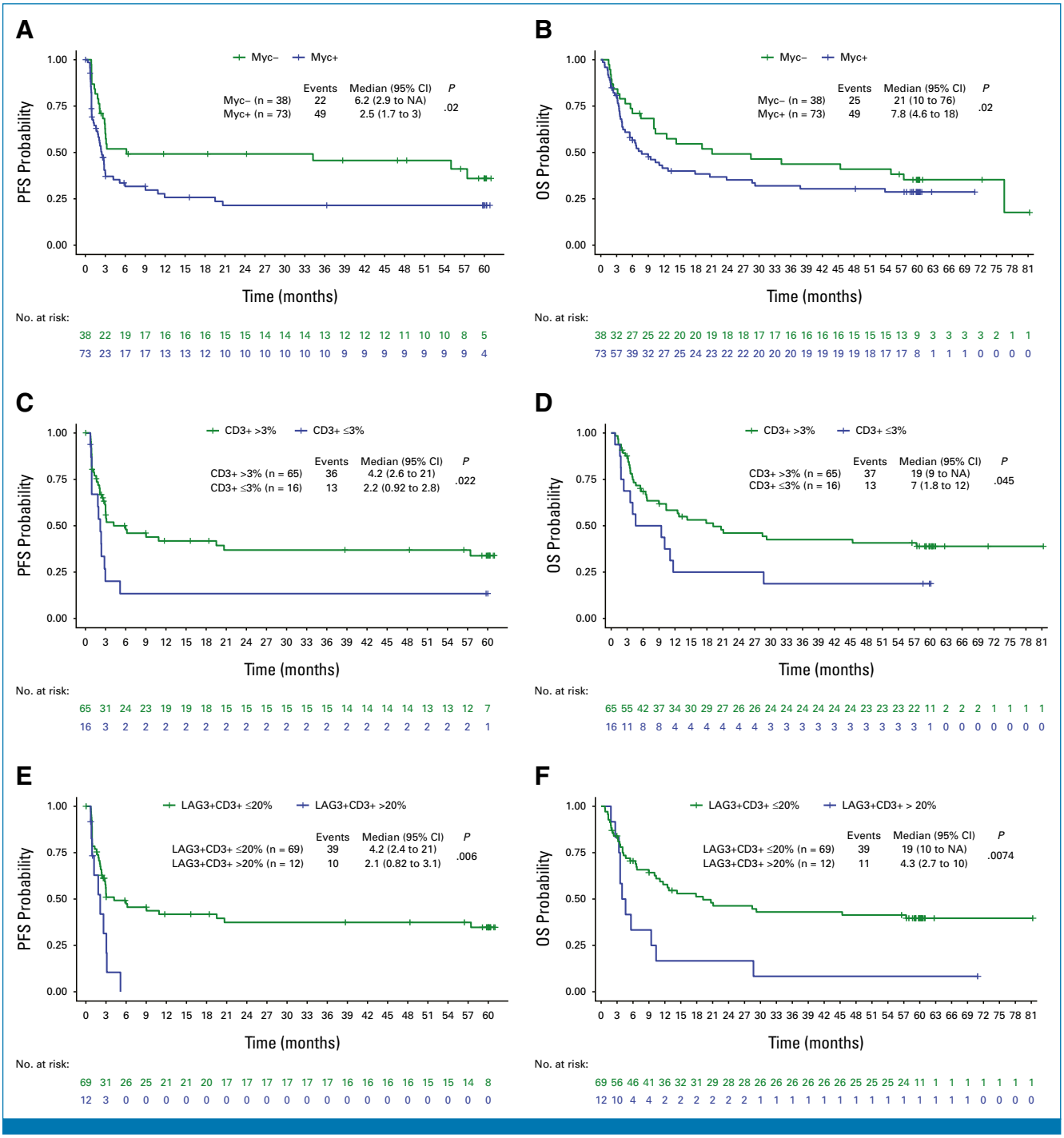

FIG 2. Baseline biomarker association with PFS and OS. (A) Kaplan-Meier plot of PFS by baseline Myc status. (B) Kaplan-Meier plot of OS by baseline Myc status. (C) Kaplan-Meier plot of PFS by percentage of tumor-infiltrating CD3+ T cells. (D) Kaplan-Meier plot of OS by percentage of tumor-infiltrating CD3+ T cells. (E) Kaplan-Meier plot of PFS by percentage of tumor-infiltrating LAG3+CD3+ T cells. (F) Kaplan-Meier plot of OS by percentage of tumor-infiltrating LAG3+CD3+ T cells. CD, cluster of differentiation; LAG3, lymphocyte-activation gene 3; NA, not available; OS, overall survival; PFS, progression-free survival. (A) is adapted from Jaeger et al.[10]

patients alive and in follow-up ≥5 years after tisagenlecleucel infusion (24/30, 80%) remained disease-free without receiving any new/additional therapy, underscoring the curative potential in a subset of patients with r/r LBCL. These results confirm the 5-year PFS and DOR previously reported for the pilot trial of tisagenlecleucel in patients with r/r LBCL (31% and 60%, respectively; ClinicalTrials.gov identifier: NCT02030834).[11]

No new or unexpected late toxicities emerged, and there was no evidence of secondary T-cell malignancies or RCL-mediated transformation, supporting the favorable long-term safety profile of tisagenlecleucel. Baseline disease and inflammatory markers, including lactate dehydrogenase and C-reactive protein, were associated with long-term benefit and may help refine patient selection (Data Supplement). CAR-T cell persistence was observed in most long-term responders with available samples; sustained remissions were seen after documented B-cell recovery.

These findings continue to demonstrate the long-term survival benefit of tisagenlecleucel without new safety signals in r/r LBCL. The results support the role of tisagenlecleucel as a transformative therapy for r/r LBCL and provide critical evidence for long-term risk-benefit assessment. The JULIET trial has been foundational in establishing CAR-T cell therapy as a curative standard-of-care option for patients with r/r LBCL in the third-line setting and provided valuable safety and scientific insights and knowledge that advanced the field, expanding the potential for CAR-T cell therapy to multiple new applications.

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DATA SHARING STATEMENT

The authors declare that all data supporting the findings of this analysis are available within the article and its appendix. Novartis is committed to sharing with qualified external researchers access to patient-level data and supporting clinical documents from eligible studies. These requests are reviewed and approved by an independent review panel on the basis of scientific merit. All data provided are anonymized to respect the privacy of patients who have participated in the trial in line with applicable laws and regulations. The data availability of these trials is according to the criteria and process described at www.clinicalstudydatarequest.com.

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