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Real-World and Clinical Trial Outcomes in Large B-cell Lymphoma with Axicabtagene Ciloleucel Across Race and Ethnicity

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Abstract:
Axicabtagene ciloleucel (axi-cel) is an autologous anti-CD19 chimeric antigen receptor (CAR) T-cell therapy approved for treatment of relapsed/refractory (R/R) large B-cell lymphoma (LBCL). Despite extensive data supporting the use of axi-cel in patients with LBCL, outcomes stratified by race and ethnicity groups are limited. Here, we report clinical outcomes with axi-cel in patients with R/R LBCL by race and ethnicity in both real-world and clinical trial settings. In the real-world setting, 1290 patients with R/R LBCL who received axi-cel between 2017-2020 were identified from the Center for International Blood and Marrow Transplant Research database; 106 and 169 patients were included from the ZUMA-1 and ZUMA-7 clinical trials, respectively. Adjusted odds ratio (OR) and hazard ratio (HR) for race and ethnicity groups are reported. Overall survival was consistent across race/ethnicity groups. However, non-Hispanic (NH) Black patients had lower overall response rate (OR, 0.37, [95% CI, 0.22-0.63]) and lower complete response rate (OR, 0.57, [95% CI, 0.33-0.97]) than NH-white patients. NH-Black patients also had a shorter progression-free survival versus NH-white (HR, 1.41, [95% CI, 1.04-1.90]) and NH-Asian patients (HR, 1.67, [95% CI, 1.08-2.59]). NH-Asian patients had a longer duration of response compared with NH-white (HR, 0.56, [95% CI, 0.33-0.94]) and Hispanic patients (HR, 0.54, [95% CI, 0.30-0.97]). There was no difference in cytokine release syndrome by race/ethnicity; however, higher rates of any-grade ICANS were observed in NH-white patients compared with other patients. These results provide important context when treating patients with R/R LBCL with axi-cel across different racial and ethnic groups. ZUMA-1 (NCT02348216) and ZUMA-7 (NCT03391466), both registered on ClinicalTrials.gov

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Short Title: Race and Ethnicity Analysis of Axi-Cel in LBCL

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Data Sharing Statement

Kite is committed to sharing clinical trial data with external medical experts and scientific researchers in the interest of advancing public health, and access can be requested by contacting medinfo@kitepharma.com.

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KEY POINTS

- Overall survival and most safety outcomes with axi-cel were consistent across race/ethnicity in relapsed/refractory large B-cell lymphoma (139 characters)
- Real-world outcomes with CAR T-cell therapy are different among non-Hispanic Black patients and may be related to barriers to access (134 characters)

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ABSTRACT
(249/250 words)

Axicabtagene ciloleucel (axi-cel) is an autologous anti-CD19 chimeric antigen receptor (CAR) T-cell therapy approved for treatment of relapsed/refractory (R/R) large B-cell lymphoma (LBCL). Despite extensive data supporting the use of axi-cel in patients with LBCL, outcomes stratified by race and ethnicity groups are limited. Here, we report clinical outcomes with axi-cel in patients with R/R LBCL by race and ethnicity in both real-world and clinical trial settings. In the real-world setting, 1290 patients with R/R LBCL who received axi-cel between 2017-2020 were identified from the Center for International Blood and Marrow Transplant Research database; 106 and 169 patients were included from the ZUMA-1 and ZUMA-7 clinical trials, respectively. Adjusted odds ratio (OR) and hazard ratio (HR) for race and ethnicity groups are reported. Overall survival was consistent across race/ethnicity groups. However, non-Hispanic (NH) Black patients had lower overall response rate (OR, 0.37, [95% CI, 0.22-0.63]) and lower complete response rate (OR, 0.57, [95% CI, 0.33-0.97]) than NH-white patients. NH-Black patients also had a shorter progression-free survival versus NH-white (HR, 1.41, [95% CI, 1.04-1.90]) and NH-Asian patients (HR, 1.67, [95% CI, 1.08-2.59]). NH-Asian patients had a longer duration of response compared with NH-white (HR, 0.56, [95% CI, 0.33-0.94]) and Hispanic patients (HR, 0.54, [95% CI, 0.30-0.97]). There was no difference in cytokine release syndrome by race/ethnicity; however, higher rates of any-grade ICANS were observed in NH-white patients compared with other patients. These results provide important context when treating patients with R/R LBCL with axi-cel across different racial and ethnic groups. ZUMA-1 (NCT02348216) and ZUMA-7 (NCT03391466), both registered on ClinicalTrials.gov

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INTRODUCTION

People from racial and ethnic minority groups across the United States (US) experience worse survival outcomes after a cancer diagnosis compared with non-Hispanic white patients.[1,2] Among patients with B-cell malignancies, use of and response rates to first-line chemoimmunotherapy (CIT) are similar across all races and ethnicities.[3] However, therapeutic approaches for relapsed or refractory (R/R) disease may be limited for people from racial and ethnic minority groups due to socioeconomic and geographic disparities.[3-5] Large B cell lymphoma (LBCL) is a common and aggressive B-cell malignancy for which 20-50% of patients develop R/R LBCL.[6]

Axicabtagene ciloleucel (axi-cel) is a CD19-directed autologous chimeric antigen receptor (CAR) T-cell therapy with a CD28 co-stimulatory domain that provides rapid and strong expansion and reprograms T-cells to trigger target-specific cytotoxicity of cancer cells. Axi-cel is approved for the treatment of adult patients with R/R LBCL after receipt of ≥2 lines of therapy based on favorable results in the pivotal Phase 1/2 ZUMA-1 study in refractory LBCL.[7,8] Its utilization was subsequently expanded for second-line treatment of primary R/R LBCL within ≤12 months from frontline therapy after demonstration of statistically significant improvements in event-free survival and overall survival (OS) in the randomized phase 3 ZUMA-7 trial of axi-cel versus standard of care.[7,9]

Due to strict eligibility criteria in clinical trials, efficacy outcomes may not always reflect real-world medical practice, where patients may exhibit more heterogenous outcomes due to biological differences, comorbidities, and racial differences.[8,10] Recently, a non-interventional post-authorization safety study (PASS) was initiated using the Center for International Blood

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and Marrow Transplant Research (CIBMTR®) registry as a prospective, long-term, non-interventional cohort study of real-world axi-cel use in LBCL and found that efficacy outcomes were consistent with the results of the ZUMA-1 clinical trial.[8]

Despite extensive data supporting the efficacy and safety of axi-cel in LBCL, sparse data are available on outcomes by race and ethnicity in clinical trials and real-world studies published to date.[7,9,11-14] Here, we examine outcomes with axi-cel in R/R LBCL by race and ethnicity in both clinical trials and real-world settings.

METHODS

Patients and Study Design

The CIBMTR is a collaborative working group of >500 treatment centers worldwide managed by the Medical College of Wisconsin and the National Marrow Donor Program (NMDP). Detailed information on patient, treatment and disease characteristics, as well as demographics were longitudinally reported by participating centers. Integrity and quality of data were monitored at different levels, including onsite audits, and automated and manual checks for discrepancies. Patients signed informed consent forms to share data with the CIBMTR for research studies, and use of these data for research was overseen by the NMDP central institutional review board. A PASS was conducted using the CIBMTR data infrastructure to prospectively capture long-term outcomes of axi-cel in the real-world, with the enrollment of 1497 patients from 79 centers completed in August 2020. Data collected for the PASS up until May 4, 2022, were used for the real-world assessment.

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In the real-world study population, patients received post-approval axi-cel per institutional practice or per protocol as part of the clinical trials. No treatments, therapy protocols, or procedures were mandated. Participating sites were responsible for the completion of data collection at predetermined time points that aligned with routine medical care. Patients who received axi-cel in a non-commercial setting, with prior history of non-transplant cellular therapy, and of unknown/other race (who were non-Hispanic and not Asian, Black, or white) or ethnicity were excluded.

Additionally, a post hoc assessment of axi-cel in R/R LBCL by race and ethnicity in eligible patients enrolled in ZUMA-1 (NCT02348216; Phases 1 and 2, Cohorts 1 and 2) and ZUMA-7 (NCT03391466; phase 3) was conducted.[7,15] Data from axi-cel treated patients enrolled in ZUMA-1 (April 2015-January 2017) and ZUMA-7 (January 2018-October 2019) were included in the clinical trial analysis.[7,15] R/R disease in ZUMA-7 was defined as patients who were refractory to first-line CIT or experienced a relapse ≤12 months after first-line CIT.[7] In ZUMA-1, refractory disease was defined as progressive or stable disease as the best response to the most recent therapy or relapse ≤12 months after autologous stem cell transplantation.[15] Eligibility criteria and data collection schedule of ZUMA-1 and ZUMA-7 trials were previously described.[7,15]

Race (Asian, Black, white, or Other) and ethnicity (Hispanic/Latino, or non-Hispanic/Latino) were self-reported. Patients treated outside of the US were excluded.

Treatment and Endpoints

In the real-world assessment, efficacy endpoints assessed in this analysis by race and ethnicity included overall response rate (ORR), complete response (CR) rate (per Lugano[16] and institution), duration of response (DOR), progression-free survival (PFS), and OS. Safety

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outcomes assessed were cytokine release syndrome (CRS) graded per Lee et al.[17] and immune effector cell-associated neurotoxicity syndrome (ICANS; per American Society for Transplantation and Cellular Therapy [ASTCT] consensus grading)[17] at follow-up 100 days post-infusion, and prolonged cytopenias (defined as failure to resolve within the first 30 days after infusion) at 30 days post-infusion. In the clinical trial analysis, ORR and CR were assessed centrally per Lugano.[16] CRS (per Lee[17]) and neurologic events (NE; graded per NCI Common Terminology Criteria for Adverse Events v4.03) were also analyzed.

Statistical Methods

Baseline characteristics, efficacy, and safety outcomes were assessed in all eligible patients for the real-world assessment and in axi-cel treated patients in ZUMA-1 Phases 1 and 2 (Cohorts 1 and 2) and ZUMA-7 for the clinical trial analysis.

For both real-world and clinical trial analyses, race (white, Black, and Asian) and ethnicity (Hispanic versus non-Hispanic) were combined as a single variable with 4 categories: non-Hispanic white, non-Hispanic Black, non-Hispanic Asian and Hispanic. Dichotomous outcomes were described using percentages with 95% exact confidence intervals. For the real-world assessment, DOR, PFS, and OS were summarized via Kaplan-Meier estimator. Time to CRS/ICANS resolution was summarized using cumulative incidence function with death without resolution as a competing risk. In the real-world analysis, multivariate logistic and Cox regression models were used to assess the associations between race and ethnicity with efficacy and safety endpoints of interest while adjusting for other potential risk factors (age, sex, Eastern Cooperative Oncology Group performance status, comorbidities, and disease and treatment characteristics; please see **Supplemental Methods** for the complete list of

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covariates). The proportionality assumption for the Cox model was tested for the main race/ethnicity variable using an interaction term with the logarithm of the event time. A stepwise variable selection process was used to determine the final list of covariates for both the logistic and Cox regression models, using a *p*-value cutoff of 0.2 for variables to enter the model and 0.05 for variables to stay in the model. Sensitivity analyses with race and ethnicity kept as separate variables were also performed. All analyses were conducted using SAS 9.4 M6.

Patients signed informed consent forms to share data with the CIBMTR for research studies, and use of these data for research was overseen by the National Marrow Donor Program central institutional review board.

RESULTS

Disposition and Baseline Characteristics

A total of 1497 patients with R/R LBCL were enrolled in the real-world cohort between October 2017 and August 2020 (**Supplement Figure 1**); 207 patients were excluded from the analysis due to histology of non-LBCL cancer (n=24), prior non-hematopoietic cell transplantation (HCT) cellular therapy (n=29), missing data on comorbidities (n=43), missing data on time from leukapheresis to infusion (n=2), no follow-up for efficacy or safety (n=5), and other or missing race/ethnicity (n=104; due to missing ethnicity [n=73], missing race [n=20], other race including Native Hawaiian/Pacific Islander [n=4], American Indian/Alaska native [n=2], and more than 1 race [n=5]). In total, 1290 patients were included in the real-world analysis. Non-Hispanic Black patients were primarily treated in centers along the east coast of

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the US, and those of Hispanic ethnicity were primarily treated on either coast or the southern regions of the US (**Figure 1**). Most patients were non-Hispanic white (77%, n=992); 12% were Hispanic (n=152), and 5% and 6% were non-Hispanic Black (n=68) and non-Hispanic Asian (n=78), respectively. Within the Hispanic ethnicity group, 69% of patients were white, 1% were Black, <1% were Asian, and 29% were of Other or Unknown races (unknown, n=28; not reported, n=12; American Indian or Alaska native, n=2; more than 1 race, n=2).

Baseline characteristics by race and ethnicity in the real world are reported in **Table 1** and consistent across non-Hispanic white, non-Hispanic Black, non-Hispanic Asian and Hispanic patient groups with a few exceptions. The median age across all groups was 62.2 years (range, 19.6-90.8). Of those included for analysis, both non-Hispanic Black patients (median age, 55.5) and Hispanic patients (median age, 58.3) were less likely to be ≥65 years of age than non-Hispanic white patients (median age, 63.0). The baseline prevalence of moderate to severe pulmonary disease was higher in non-Hispanic Black patients (41%) than non-Hispanic white patients (29%), though the prevalence of prior malignancies was lower (6% versus 17%, respectively). Hispanic patients had a lower prevalence of moderate to severe pulmonary disease (20%) and prior malignancy (7%) compared with non-Hispanic white patients. Furthermore, 75% of non-Hispanic Black, 60% of non-Hispanic Asian and 58% of non-Hispanic white and Hispanic patients received axi-cel infusion ≥12 months after diagnosis.

A total of 106 patients were included from ZUMA-1 (data cutoff date: August 11, 2018) and 169 patients from ZUMA-7 (data cutoff date: March 18, 2021). The median age of patients included from ZUMA-1 and ZUMA-7 was 58 years (range, 23-76) and 59 years (range, 21-80), respectively. Within the Hispanic group of ZUMA-1, 68% of patients were of white race and 32%

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were reported as other or unknown. In ZUMA-7, within the Hispanic group, 60% of patients were white, 10% were Black, and 30% were of other or unknown races. More baseline details on patients included from clinical trials with axi-cel can be found in **Supplemental Table 1**.

Efficacy

The median follow-up for patients receiving axi-cel within the real-world cohort was 24.3 months (95% CI, 24.2-24.5). ORR was 75% (CR rate, 59%), 54% (CR rate, 46%), 71% (CR rate, 58%), and 73% (CR rate, 57%) in non-Hispanic white, non-Hispanic Black, non-Hispanic Asian, and Hispanic patients, respectively (**Figure 2a**). The median DOR in non-Hispanic white patients was 23.6 months (95% CI, 17.8-31.3), in non-Hispanic Black patients, 22.6 months (95% CI, 6.5-not estimable [NE]), in non-Hispanic Asian patients, not reached (95% CI, 25.3-NE), and in Hispanic patients, 21.3 months (95% CI, 16.4-NE; **Figure 3a**). The 12-month event-free probability of DOR for each racial and ethnic minority group was higher among non-Hispanic Asian patients (78%) compared to non-Hispanic Black (58%), non-Hispanic white (59%), and Hispanic patients (64%). Median PFS was 9.3 months (95% CI, 6.5-12.7) in non-Hispanic white patients and 3.8 months (95% CI, 2.9-8.5), 21.7 months (95% CI, 3.3-NE), and 7.8 months (95% CI, 4.1-17.4) for non-Hispanic Black, non-Hispanic Asian, and Hispanic patients, respectively (**Figure 3b**). Median OS was 25.9 months (95% CI, 20.7-31.4) in non-Hispanic white patients, 28.0 months (95% CI, 8.3-NE) in non-Hispanic Black patients, 24.7 months (95% CI, 16.0-NE) and 19.3 months (95% CI, 13.6-29.3) in Hispanic patients (**Figure 3c**). The 24-month PFS rate was generally consistent among all patients, except among non-Hispanic Black patients, and the cumulative incidence of relapse was higher among non-Hispanic Black patients (**Figure 4a, Supplemental Table 2**). The primary cause of death was lymphoma-related in 71% of non-

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Hispanic white, 73% of non-Hispanic Black, 60% of non-Hispanic Asian, and in 71% of Hispanic patients. Non-adjusted OR/HRs are reported in **Supplemental Table 7**.

After multivariate adjustment (**Figure 4a**), non-Hispanic Black patients had statistically lower ORR than non-Hispanic white (odds ratio [OR], 0.37; 95% CI, 0.22-0.63), non-Hispanic Asian (OR, 0.45; 95% CI, 0.22-0.94), and Hispanic patients (OR, 0.45; 95% CI, 0.24-0.84); a lower CR rate than non-Hispanic white patients (OR, 0.57; 95% CI, 0.33-0.97); and a shorter PFS than non-Hispanic white (HR, 1.41; 95% CI 1.04-1.90) and non-Hispanic Asian patients (HR, 1.67; 95% CI, 1.08-2.59). Non-Hispanic Asian patients had a longer DOR than non-Hispanic white (HR, 0.56; 95% CI, 0.33-0.94) and Hispanic patients (HR, 0.54; 95% CI, 0.30-0.97). There was a trend towards longer DOR in Non-Hispanic Asian patients when compared to non-Hispanic Black patients (HR, 0.51; 95% CI, 0.26-1.00). No statistical differences were found in OS across all race and ethnicity, or in any efficacy outcome between Hispanic and non-Hispanic white patients. In a sensitivity analysis with race and ethnicity separated as two variables, efficacy results were consistent with the main analysis of the real-world assessment (**Supplemental Table 3**).

In ZUMA-1 (n=99), CR rates were reported as the following among non-Hispanic white (n=74; ORR, 73%; CR rate, 55%), non-Hispanic Black (n=4; ORR, 100%; CR rate, 100%), non-Hispanic Asian (n=3; ORR, 67%; CR rate, 67%) and Hispanic patients (n=18, ORR, 78%; CR rate, 44%; **Figure 2b**). Among patients who received axi-cel in ZUMA-7 (n=169), ORR remained largely consistent across all race and ethnicity groups (range, 80%-83%; **Figure 2c**); with the following CR rates among non-Hispanic Black (CR rate, 70%), non-Hispanic white (CR rate, 66%), non-Hispanic Asian (CR rate, 58%), and Hispanic patients (CR rate, 50%). In a sensitivity analysis with race and ethnicity separated as two variables, efficacy results were consistent with the

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main analysis of clinical trials (**Supplemental Table 4**).

Safety

As shown in **Table 2**, CRS rates were generally similar in all patients who received axi-cel in the real-world assessment; 83% in non-Hispanic white (grade ≥3, 9%), 82% in non-Hispanic Black (grade ≥3, 6%), 90% in non-Hispanic Asian (grade ≥3, 10%) and 81% in Hispanic patients (grade ≥3, 5%). The median time to onset of CRS post-infusion was 4 days (range, 1.0-73.0) between race and ethnicity groups and most cases resolved within 3 weeks of onset regardless of race or ethnicity. Rate of ICANS of all grade and Grade 3 in patients were reported as the following: non-Hispanic white, 59% (grade ≥3, 29%); non-Hispanic Black, 40% (grade ≥3, 19%); non-Hispanic Asian, 45% (grade ≥3, 21%); Hispanic, 43% (grade ≥3, 16%; **Table 2**). The median time to onset of ICANS was 7 days (range, 1.0-36.0), and median time to resolution was 8 days (range, 1.0-115.0) after onset. For the treatment of CRS or ICANS, 59% of patients received tocilizumab and 48% received corticosteroids (**Table 2**). Prolonged neutropenia and prolonged thrombocytopenia (among patients who survived Day 30 post-infusion) was generally similar across all patients (**Table 2**). Non-adjusted OR/HRs are reported in **Supplemental Table 7**.

Safety analyses with multivariate adjustment are briefly described in **Figure 4b** and included in the supplement (**Supplemental Tables 5 and 6**). No differences were observed for CRS (any-grade or grade ≥3) or prolonged neutropenia by race or ethnicity. Non-Hispanic Asian, non-Hispanic Black, and Hispanic patients had a lower risk of any-grade ICANS versus non-Hispanic white patients (non-Hispanic Asian, OR 0.56 [95% CI, 0.35-0.90]; non-Hispanic Black, OR 0.54 [95% CI, 0.32-0.91]; Hispanic, OR 0.58 [95% CI, 0.40-0.82]). Hispanic patients also had lower risk of grade ≥3 ICANS (OR 0.45 [95% CI, 0.28-0.71]) versus non-Hispanic white patients.

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Non-Hispanic Asian patients had a higher incidence of thrombocytopenia than both non-Hispanic white (OR, 1.77; 95% CI, 1.02-3.09) and non-Hispanic Black patients (OR, 2.5; 95% CI, 1.07-5.83). Safety outcomes in the sensitivity analysis were also consistent with the main analysis (**Supplemental Table 5**).

In ZUMA-1 (n=106), CRS rates were 92% (grade ≥3, 13%) in non-Hispanic white, 100% (grade ≥3, 40%) in non-Hispanic Black, 67% (no grade ≥3) in non-Hispanic Asian, and 95% (no grade ≥3) in Hispanic patients. NEs developed in 72% (grade ≥3, 34%) of non-Hispanic white, 80% (grade ≥3, 60%) of non-Hispanic Black, 33% (no grade ≥3) of non-Hispanic Asian, and 47% (grade ≥3, 21%) of Hispanic patients (**Table 3**).

In ZUMA-7 (n=159), CRS rates and NEs were also generally similar across groups (**Table 3**). CRS rates were 92% (grade ≥3, 5%) in non-Hispanic white, 88% (no grade ≥3) in non-Hispanic Black, and 100% in non-Hispanic Asian (grade ≥3, 9%) and Hispanic patients (grade ≥3, 13%). In total, 59% (grade ≥3, 21%) of non-Hispanic white, 50% (grade ≥3, 25%) of non-Hispanic Black, 45% (grade ≥3, 18%) of non-Hispanic Asian, and 100% (grade ≥3, 25%) of Hispanic patients developed NEs in the ZUMA-7 trial. In a sensitivity analysis with race and ethnicity separated as 2 variables, safety results were consistent with the main analysis (**Supplemental Table 6**).

DISCUSSION

In the real-world cohort and the ZUMA-1 and ZUMA-7 clinical trials, OS and most safety outcomes of axi-cel in patients with R/R LBCL were consistent across all racial and ethnic groups included in this analysis. In the real-world cohort, lower rates of response and PFS were observed among non-Hispanic Black patients compared with non-Hispanic white patients,

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though these differences did not translate to a difference in OS. Additionally, non-Hispanic Asian patients had a significantly longer DOR compared with non-Hispanic white and Hispanic patients, with a trend towards longer DOR compared with non-Hispanic Black patients.

There were no significant differences in rates of CRS or prolonged neutropenia in patients treated with axi-cel by race or ethnicity in both the real-world and clinical trial analysis. However, in the real-world cohort, non-Hispanic Black and non-Hispanic Asian patients had a lower incidence of any-grade ICANS than non-Hispanic white patients. These results in non-Hispanic Asian patients were consistent with outcomes in a recent study on Chinese patients with R/R non-Hodgkin lymphoma (NHL) treated with axi-cel, in which lower rates of any grade NEs (n=17, 16.2%) were reported.[18] Hispanic patients also had a lower incidence of any-grade and grade ≥3 ICANS. Furthermore, non-Hispanic Asian patients had a higher rate of prolonged thrombocytopenia than non-Hispanic white or non-Hispanic Black patients.

In the current analysis, the proportions of non-Hispanic Black, non-Hispanic Asian and Hispanic patients were comparable between the real-world setting (5-12%) and clinical trials (5-11%). The population expected to be Hispanic from the SEER estimation (10.95% of 1500 patients) was similar to proportion of Hispanic patients included in this analysis (11.78% in the real-world and 10.55% in the clinical trial analyses). However, the proportion of non-Hispanic Black patients in the real-world analysis (5.27% of 1290) and clinical trial analysis (5.45% of 275 from ZUMA-1 and ZUMA-7 combined) was inconsistent with the proportion of the Black population in the US diagnosed with LBCL and numerically lower than a recent SEER estimation of disease prevalence in this population (7.24% of 1500 patients with LBCL were expected to be Non-Hispanic Black).[19] The sample size for other races (eg, Pacific Islander, Native Americans)

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was too small to be evaluated in the current study. Differences in axi-cel treatment among racial and ethnic minorities may be further exacerbated by inaccuracies in the recording of patient race or ethnicity due to the lack of a standardized demographic data collection process.[20]

Age also impacts cancer mortality, and the median age of non-Hispanic Black patients in the current analysis was numerically lower than that of non-Hispanic white patients.[21] Generally, Black patients are more likely to be diagnosed with DLBCL at a younger age, have stage 3-4 disease, and have a worse 5-year survival rate relative to white patients.[22] However, in the ZUMA-1 and ZUMA-7 clinical trials, older age did not impact efficacy with axi-cel and a manageable safety profile was maintained in all patients with R/R LBCL ≥65 years of age.[23,24]

Additionally, in the real-world cohort, a larger proportion of non-Hispanic Black patients had ≥12-month timeframes from diagnosis to infusion compared with all other patients, suggesting axi-cel may have been reserved as a treatment option in later lines of therapy. Barriers to treatment access among non-Hispanic Black patients may not be specific to CAR T-cell therapy alone, but extend throughout the course of therapy.[3,20] In light of this, and taking into consideration that non-Hispanic Black patients also experienced lower response rates, shorter PFS, and a greater proportion of patients waited ≥28 days from leukapheresis to lymphodepleting chemotherapy compared with other racial and ethnic groups, it is imperative to understand treatment access barriers that may differentially impact diverse patient populations.

Several factors disproportionately affect patients from racial and ethnic minority groups that may account for the underrepresentation of these patients in clinical trials.[3,25-28] In the

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real-world cohort, numerically higher rates of non-Hispanic Black patients did not meet eligibility criteria for the ZUMA-1 trial compared with all other patients. Historically, factors such as higher poverty levels, poorer community health status, employment, education, and insufficient caregiver support[25] were considered major barriers to clinical trial enrollment, particularly among non-Hispanic Black patients.[3,25,26] Based on a SEER-based report, proximity to authorized treatment centers alone was insufficient to explain underrepresentation of minority patients in trial participation and optimal access to care.[19] Furthermore, although race and ethnicity have been consistently associated with poorer outcomes and an absence of adequate treatment, a higher cancer burden and mortality rate may also be closely linked to negative social determinants of health. This includes low income (<$25,000 yearly), lack of health insurance, and living in states with poorer socioeconomic status and inadequate public health infrastructure.[26]

A study from the ASTCT-NMDP ACCESS Initiative assessing barriers to HCT and CAR T-cell therapy found that many states across the US have potentially discriminatory policy restrictions and inadequate support for patients and their caregivers (eg, non-coverage if patient has a child with non-suitable family support or history of mental illness) that result in financial burden when seeking these treatments.[29] Timely allogeneic and autologous HCT is particularly low in Black patients compared with white patients.[30,31] This can impact rate of survival 1-year post transplant[33,34] and access to proper post-transplant therapies.[28,33,35] Access to timely HCT therapy is crucial for the post-HCT journey in patients with hematologic malignancies. With respect to CAR T-cell therapy, the ASTCT-NMDP ACCESS Initiative also found that Black patients

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were more likely to travel longer distances to receive this therapy and, in general, were less likely to actually be treated.[36]

CAR T-cell therapy is costly and, in the US, medical insurance coverage varies by race and ethnicity.[37] A recent report of US patients showed that those receiving CAR T-cell therapy were more likely to have commercial insurance and less likely to be uninsured or covered by Medicare.[38] Furthermore, given the high out-of-pocket cost for CAR T-cell therapy that includes expenses for travel or hospitalization, inadequate insurance coverage (which do not cover these expenses) further limit access to treatment for minority groups.[38] Additional areas of inclusivity research related to CAR T-cell therapy are needed, with a focus on promoting timely referral of patients from racial/ethnic minority groups, reporting whether access for minority groups is improving over time, and describing any disparities related to delivery of the CAR T-cell product for infusion. Identification of other disparities related to race, ethnicity, and socioeconomic status in the setting of CAR T-cell therapy is also important to close treatment gaps and help promote equal, inclusive treatment strategies. Healthcare providers may consider developing active inclusion strategies to limit race- and ethnicity-based social deterrents to CAR T-cell therapy to benefit a broader range of patients.[22,26,39] A successful treatment approach may also include patient-specific screening; for example, based on the safety findings with axi-cel in this study, risk factors for thrombocytopenia could be assessed in all non-Hispanic Asian patients.[26]

As with all observational studies, this analysis had some key limitations. In both the real-world and clinical trial assessments, race and ethnicity were self-reported, with no standardized definitions, potentially leading to biases and variability in reporting. CIBMTR reporting was not mandatory and results may not be reflective of the entirety of axi-cel usage and outcomes in

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the US. Due to the small sample size of racial/ethnic minority groups in the clinical trial analysis, confidence intervals were wide and time to event analyses could not be conducted. The analysis only included patients treated in the US and thus results may not be globally applicable but may provide context in different geographic locations.[40] Finally, this analysis did not include patient reported outcomes or quality-of-life endpoints.

Overall, outcomes with axi-cel CAR T-cell therapy in R/R LBCL were mostly consistent between races and ethnicities reported here, with some exceptions among non-Hispanic Black patients. These results provide important context regarding barriers of access to therapies for lymphoma to help develop interventions that improve health care access for all patients.

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AUTHORSHIP CONTRIBUTIONS

FLL, TS, ZHH, HW, EB, HM, CS, HX, MCP designed the study. MCP, HM, HW, ZHH, HX acquired and assembled data. ZHH, HW, EB analyzed data and prepared the analysis reports. All authors were involved in the interpretation of the data and writing of the article and provided final approval to submit for publication.

CONFLICT OF INTEREST DISCLOSURES

FLL had a scientific advisory role/consulting role with A2, Allogene, Amgen, bluebird bio, BMS/Celgene, Calibr, Caribou, Cellular Biomedicine Group, Cowen, Daiichi Sankyo, EcoR1, Emerging Therapy Solutions, GammaDelta Therapeutics, Gerson Lehrman Group (GLG), Iovance, Kite Pharma, Janssen, Legend Biotech, Novartis, Sana, Takeda, Wugen, Umoja; patents, royalties, other intellectual property in several patents held by the institution in my name (unlicensed) in the field of cellular immunotherapy; travel support from A2 Bio; and other relationships with Allogene (Institutional), Aptitude Health, ASH, bluebird bio (Institutional), BioPharma Communications CARE Education, BMS (Institutional), CERo Therapeutics (Institutional), Clinical Care Options Oncology, Imedex, Kite, a Gilead Company (Institutional), Novartis (Institutional), National Cancer Institute, Leukemia and Lymphoma Society, Society for Immunotherapy of Cancer. **TS** had a consultancy or advisory role for AbbVie, AstraZeneca,

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TABLES

Table 1. Baseline Characteristics by Race and Ethnicity in the Real-World

Key Variable of Interest, n (%) unless specified	Hispanic (n=152)	Non-Hispanic Asian (n=78)	Non-Hispanic Black (n=68)	Non-Hispanic white (n=992)
Age, median (range), years	58.3 (23.9-80.6)	61.8 (21.5-82.1)	55.5 (21.5-84.4)	63.0 (19.6-90.8)
Age ≥65 years	37 (24)	27 (35)	16 (24)	411 (41)
Male sex	98 (64)	41 (53)	42 (62)	663 (67)
ECOG PS ≥2 before infusion	4 (3)	9 (12)	1 (1)	44 (4)
Elevated LDH at initial diagnosis	38 (25)	22 (28)	17 (25)	303 (31)
HCT-CI score prior to infusion				
0	67 (44)	29 (37)	16 (24)	300 (30)
1	24 (16)	17 (22)	11 (16)	178 (18)
2	32 (21)	9 (12)	10 (15)	115 (12)
≥3	29 (19)	23 (29)	31 (46)	399 (40)
Disease histology at diagnosis				
DLBCL	119 (78)	61 (78)	61 (90)	803 (81)
PMBCL	4 (3)	2 (3)	2 (3)	30 (3)
HGBL	29 (19)	15 (19)	5 (7)	159 (16)
With *MYC* and *BCL2* and/or *BCL6* rearrangements	26 (17)	13 (17)	4 (6)	147 (15)
NOS	3 (2)	2 (3)	1 (1)	12 (1)
Key comorbidities[a]				
Pulmonary, moderate to severe	30 (20)	14 (18)	28 (41)	289 (29)

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Prior cancer	10 (7)	8 (10)	4 (6)	166 (17)
Obesity (BMI >35 kg/m^2)	15 (10)	1 (1)	9 (13)	90 (9)
Renal, moderate to severe, or prior renal implant	2 (1)	1 (1)	1 (1)	28 (3)
Histologic transformation	37 (24)	18 (23)	17 (25)	300 (30)
Disease sensitivity before infusion				
Sensitive	44 (29)	19 (24)	16 (24)	213 (21)
Resistant	93 (61)	53 (68)	46 (68)	662 (67)
Unknown	15 (10)	6 (8)	6 (9)	117 (12)
No. of lines of prior therapies, median (range)	3 (2-8)	3 (1-12)	3 (1-8)	3 (1-18)
1-2	40 (26)	19 (24)	17 (25)	275 (28)
≥3	102 (67)	54 (69)	49 (72)	691 (70)
Unknown	10 (7)	5 (6)	2 (3)	26 (3)
Prior HCT (any type)	32 (21)	22 (28)	17 (25)	305 (31)
Prior ASCT	31 (20)	21 (27)	17 (25)	290 (29)
Bridging therapy (any type)[b]	31 (20)	12 (15)	11 (16)	224 (23)
Year of axi-cel infusion				
2018 or before	46 (30)	20 (26)	21 (31)	284 (29)
2019	66 (43)	36 (46)	29 (43)	466 (47)
2020	40 (26)	22 (28)	18 (26)	242 (24)
≥12 Months from diagnosis to infusion	88 (58)	47 (60)	51 (75)	572 (58)
≥28 Days from leukapheresis to lymphodepleting	75 (49)	37 (47)	42 (62)	488 (49)

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chemotherapy				
Estimated trial eligibility for ZUMA-1[c]				
Eligible	80 (53)	39 (50)	23 (34)	426 (43)
Ineligible	72 (47)	39 (50)	45 (66)	566 (57)

[a] Comorbidities were assessed per Sorror et al 2013.[41]

[b] The incidence of bridging therapy was derived from the number of patients who initiated a prior therapy after leukapheresis and before conditioning chemotherapy.

[c] The rates of ZUMA-1 trial eligibility used adapted eligibility criteria and were estimated based on available registry data.

ASCT, autologous stem cell transplantation; BMI, body mass index; DLBCL, diffuse large B-cell lymphoma; ECOG PS, Eastern Cooperative Oncology Group performance status; HCT, hematopoietic cell transplantation; HCT-CI, hematopoietic cell transplantation-specific comorbidity index; HGBL, high-grade B-cell lymphoma; LDH, lactate dehydrogenase; No., number; NOS, not otherwise specified; PMBCL, primary mediastinal large B-cell lymphoma.

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Table 2. Safety Outcomes by Race and Ethnicity in the Real World

n (%)	Hispanic (n=152)	Non-Hispanic Asian (n=78)	Non-Hispanic Black (n=68)	Non-Hispanic white (n=992)
Any-grade CRS[a]	123 (81)	70 (90)	56 (82)	824 (83)
Grade ≥3 CRS	7 (5)	8 (10)	4 (6)	89 (9)
Any-grade ICANS	65 (43)	35 (45)	27 (40)	584 (59)
Grade ≥3 ICANS	24 (16)	16 (21)	13 (19)	285 (29)
Management of CRS and ICANS				
Tocilizumab	94 (62)	54 (69)	38 (56)	571 (58)
Corticosteroids	55 (36)	42 (54)	19 (28)	509 (51)
Prolonged cytopenia[b]	37 (25) (n=148)	25 (36) (n=70)	13 (20) (n=66)	234 (24) (n=957)
Neutropenia	11 (7)	5 (7)	3 (5)	67 (7)
Thrombocytopenia	35 (24)	23 (33)	11 (17)	215 (22)

CRS was graded per Lee et al.[42] and ICANS were graded per ASTCT consensus grading.[17]

[a] Reported on the 100-day follow-up case-report form.

[b] Defined as failure to resolve within the first 30 days after infusion, measured among patients who survived day 30 post-infusion.

ASTCT, American Society for Transplantation and Cellular Therapy; CRS, cytokine release syndrome; ICANS, immune effector cell–associated neurotoxicity syndrome.

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Table 3. Safety Outcomes by Race and Ethnicity in Clinical Trials

n (%)	Hispanic	Non-Hispanic Asian	Non-Hispanic Black	Non-Hispanic white
ZUMA-1	**n=19**	**n=3**	**n=5**	**n=79**
Any-grade CRS	18 (95)	2 (67)	5 (100)	73 (92)
Grade ≥3 CRS	0	0	2 (40)	10 (13)
Any-grade NEs	9 (47)	1 (33)	4 (80)	57 (72)
Grade ≥3 NEs	4 (21)	0	3 (60)	27 (34)
ZUMA-7	**n=8**	**n=11**	**n=8**	**n=132**
Any-grade CRS	8 (100)	11 (100)	7 (88)	121 (92)
Grade ≥3 CRS	1 (13)	1 (9)	0	7 (5)
Any-grade NEs	8 (100	5 (45)	4 (50)	78 (59)
Grade ≥3 NEs	2 (25)	2 (18)	2 (25)	28 (21)

CRS was graded per Lee et al[42] and NEs were graded per ASTCT consensus grading.[17]

ASTCT, American Society for Transplantation and Cellular Therapy; CRS, cytokine release syndrome; NE, neurologic event.

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FIGURE LEGENDS

Figure 1. Patient Geographic Distribution in the Real World and Clinical Trials. The race and ethnicity distributions of patients enrolled in the real world (orange circles) and clinical trial (teal circles) settings within authorized treatment centers at the city level are shown. The size of the circle is commensurate with the number of patients enrolled in that setting. RWE, real-world evidence.

Figure 2. Response by Race and Ethnicity in the Real World and Clinical Trials. Per central assessment. CR, complete response; ORR, overall response rate.

Figure 3. Duration of Response (A), Progression-Free Survival (B), and Overall Survival (C) by Race and Ethnicity in the Real World. CR, complete response; DOR, duration of response; OS, overall survival; PFS, progression-free survival; PR, partial response.

Figure 4. Outcomes From the Real World With Multivariable Adjustment. Adjusted odds ratios for ORR, CR Rate, and hazard ratios for DOR, PFS, and OS (A) and adjusted odds ratio for CRS, ICANS, prolonged neutropenia and prolonged thrombocytopenia (B)**.** [a] Additional covariates associated with efficacy outcomes were adjusted (data not shown). [b] OR was used for the analysis of ORR and CR and HR was used for the analysis of DOR, PFS, and OS. [c] Variables with multivariate P<.05. CR, complete response; CRS, cytokine release syndrome; DOR, duration of response; HR, hazard ratio; ICANS, immune effector cell–associated neurotoxicity syndrome;

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NHA, non-Hispanic Asian; NHB, non-Hispanic Black; NHW, non-Hispanic white; OR, odds ratio; ORR, overall response rate; OS, overall survival; PFS, progression-free survival.

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Figure 1

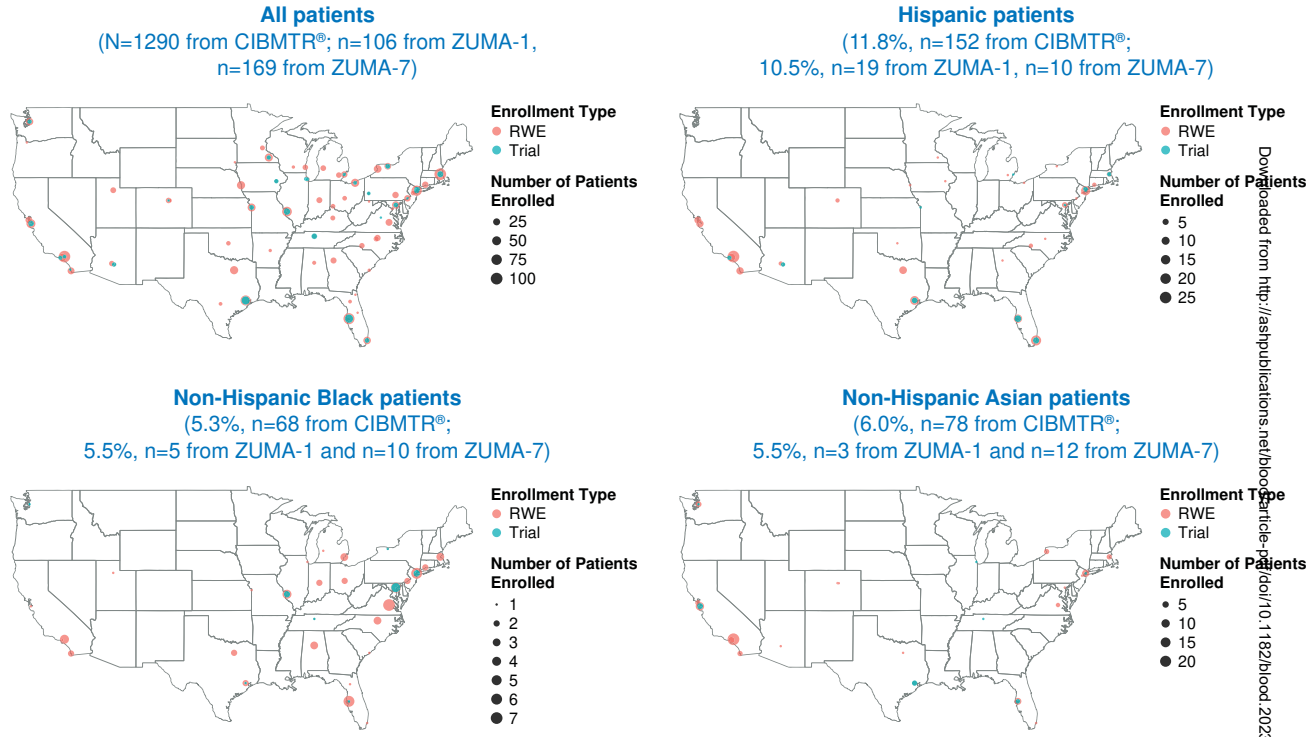

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Figure 2

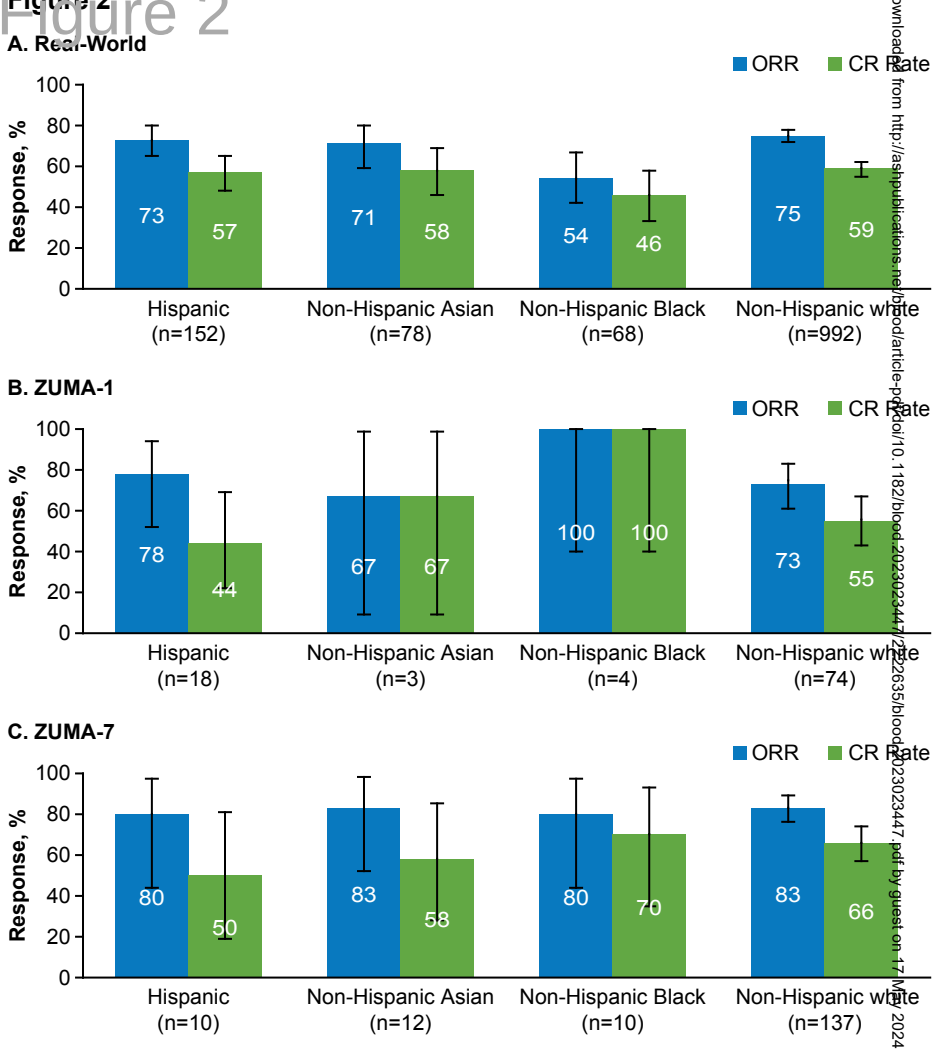

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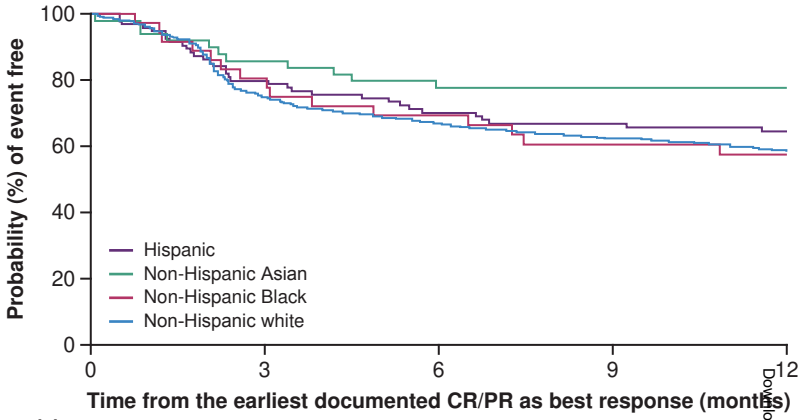
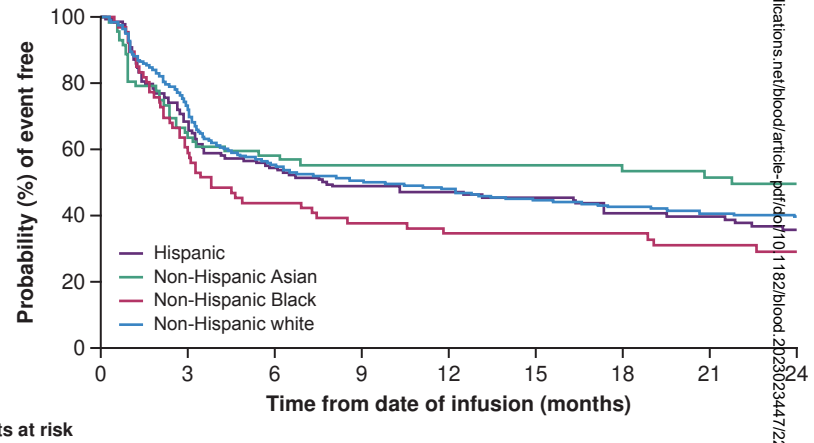
Figure 3

A. DOR



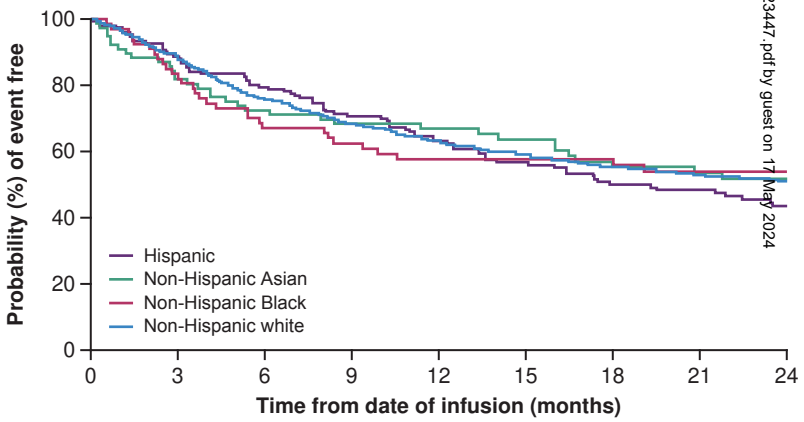
Patients at risk					
Hispanic	97	75	64	60	47
Non-Hispanic Asian	50	42	37	36	28
Non-Hispanic Black	36	29	24	21	19
Non-Hispanic white	691	504	436	391	313

B. PFS



Patients at risk									
Hispanic	144	97	76	67	61	49	43	40	31
Non-Hispanic Asian	72	46	42	39	36	29	28	27	17
Non-Hispanic Black	67	39	29	24	22	20	20	17	13
Non-Hispanic white	952	677	505	455	403	323	301	278	223

C. OS



Patients at risk									
Hispanic	152	135	119	105	87	68	59	54	39
Non-Hispanic Asian	78	62	55	51	47	38	33	31	20
Non-Hispanic Black	68	55	44	40	35	33	31	27	22
Non-Hispanic white	992	862	723	638	554	432	398	368	293

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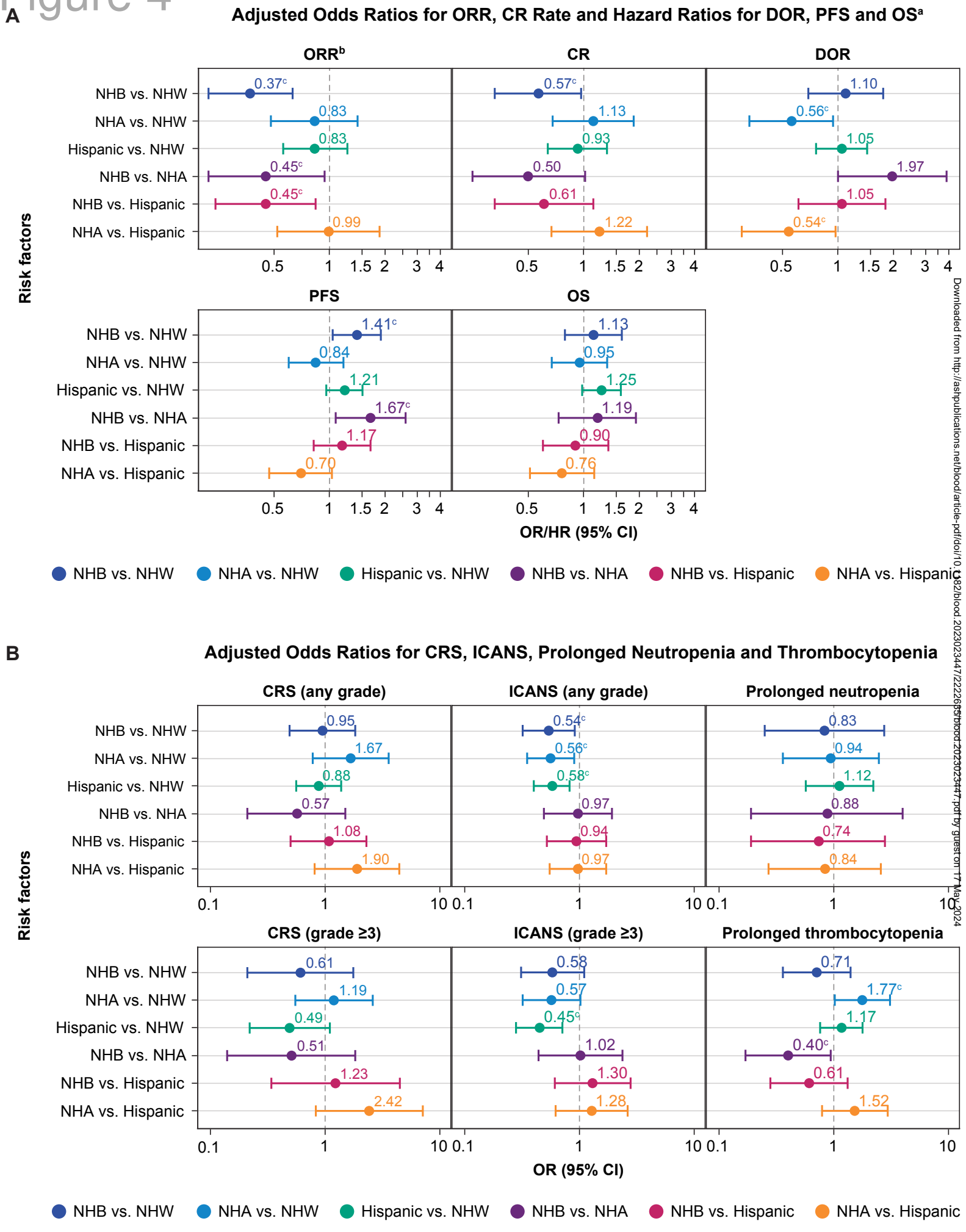
Figure 4



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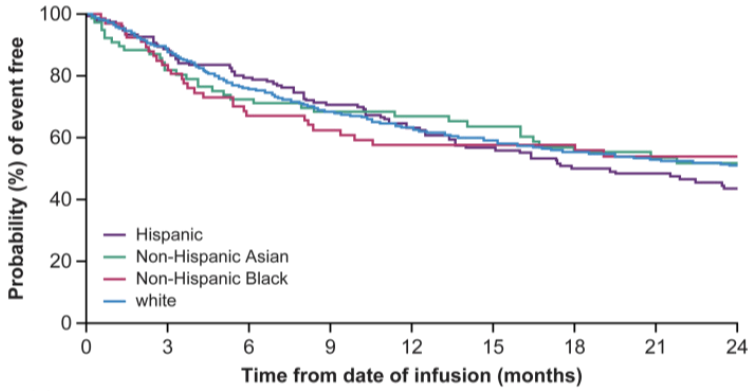
Real-World and Clinical Trial Outcomes of Axicabtagene Ciloleucel Treatment in Patients with Large B-Cell Lymphoma (LBCL) Across Race and Ethnicity

Patient populations

	Real-World	Clinical Trials	
	CIBMTR	Phase 1 & 2 ZUMA-1	Phase 3 ZUMA-7
Patient enrollment period	Aug 2020-May 2022	Apr 2015-Jan 2017	Jan 2018-Oct 2019
Number of patients included	1290	106	169
Race/Ethnicity categories	non-Hispanic white (NHW), non-Hispanic Black (NHB), non-Hispanic Asian (NHA) and Hispanic		

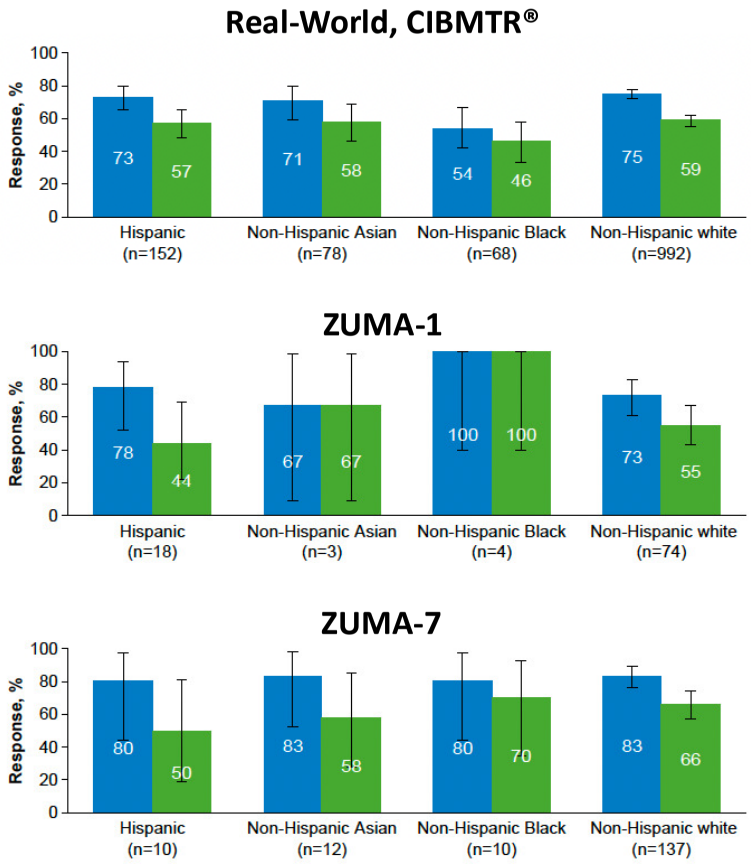
Overall survival (OS) was consistent across race and ethnic groups in the real world



Patients at risk

Hispanic	152	135	119	105	87	68	59	54	39
Non-Hispanic Asian	78	62	55	51	47	38	33	31	20
Non-Hispanic Black	68	55	44	40	35	33	31	27	22
white	992	862	723	638	554	432	398	368	293

Lower overall response rate (ORR) and complete response (CR) rates were observed among NHB patients in the real-world analysis



Conclusions: 1) **In patients with relapsed/refractory LBCL treated with axi-cel, overall survival and most safety outcomes were largely consistent across race/ethnicity. 2) Some real-world outcomes were different among non-Hispanic Black patients.**

*Locke et al. DOI: 10.xxxx/**blood**.2024xxxxxx*

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Blood Visual Abstract