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Real-World Evidence of Axicabtagene Ciloleucel for the Treatment of Large B-Cell Lymphoma: Subset Analysis of Patients With Asian Descent

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BACKGROUND

- Axicabtagene ciloleucel (axi-cel), an autologous anti-CD19 chimeric antigen receptor T-cell therapy, is a standard-of-care treatment for relapsed or refractory (R/R) large B-cell lymphoma (LBCL) after 2 or more lines of systemic therapy
- A post-approval observational safety study of commercial axi-cel use among patients with R/R LBCL was recently completed, and results from 79 centers were reported from the Center for International Blood and Marrow Transplant Research (CIBMTR)[1]
- In ZUMA-1, the pivotal Phase 1/2 study of axi-cel in refractory LBCL, and in real-world reports, efficacy and safety outcomes were evaluated for all patients, irrespective of race or ethnic group[1-3]

OBJECTIVE

- To describe real-world safety and efficacy outcomes of axi-cel use among patients of Asian descent treated in the United States

METHODS

Endpoints of Interest

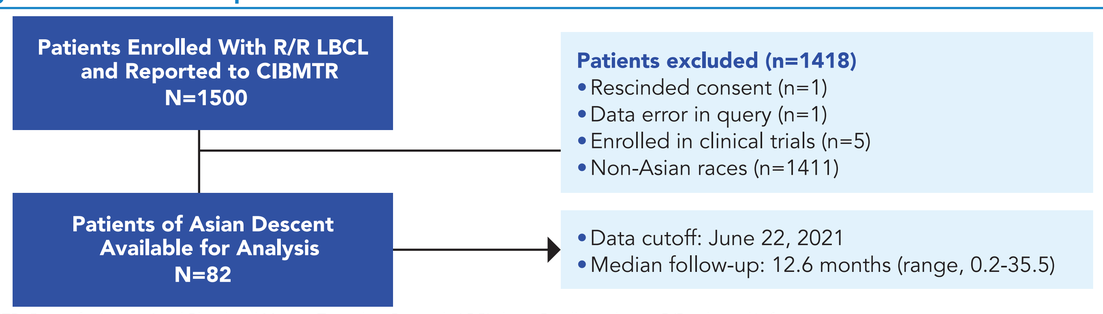
- Efficacy
  - Objective response rate (ORR): combined rate of complete response (CR) and partial response (PR)
  - Duration of response (DOR): only for patients who experienced CR or PR; time from the first CR or PR to relapse or progressive disease (PD) through radiological and/or clinical assessment, or death due to primary disease
    - DOR was censored at subsequent cellular therapy or hematopoietic cell transplantation
  - Progression-free survival (PFS): time from the first commercial axi-cel infusion to the earliest documented relapse or PD through radiological and/or clinical assessment or death due to any cause
    - PFS was censored at subsequent cellular therapy or hematopoietic cell transplantation
  - Overall survival (OS): time from the first commercial axi-cel infusion to death due to any cause
- Safety
  - Cytokine release syndrome (CRS): graded according to Lee et al.[4] Resolution of CRS was defined as the time from onset of the earliest symptom to resolution of CRS
  - Immune effector cell-associated neurotoxicity syndrome (ICANS): graded according to American Society for Transplantation and Cellular Therapy consensus criteria.[5] Resolution of ICANS was defined as the time from onset of the earliest symptom to resolution of ICANS

Statistical Analysis

- Baseline categorical variables: frequencies and percentages
- Baseline continuous variables: medians, minimums, and maximums
- ORR, CR rate, CRS rate, and ICANS rate: frequencies and percentages along with Fisher's exact 95% CIs
- DOR, PFS, and OS: Kaplan-Meier estimates and 95% CIs
- CRS and ICANS resolution rates: cumulative incidence functions and 95% CIs

RESULTS

Figure 1. Patient Disposition



CIBMTR, Center for International Blood and Marrow Transplant Research; LBCL, large B-cell lymphoma; R/R, relapsed/refractory.

- Patients enrolled with R/R LBCL were treated with axi-cel at 79 centers between October 2017-August 2020
  - The data cutoff date was June 22, 2021 (**Figure 1**)
- A total of 82 patients of Asian descent treated at 24 centers were available for the analysis

Table 1. Patient Demographics

Characteristic	Patients of Asian Descent N=82
Median age (range), years ≥65 years, %	60.7 (21.5-82.1) 34
Male, %	54
ECOG performance status 0-1, %	83
Prior malignancy, %	10
Transformed lymphoma, %	23
Double- or triple-hit, %	15
Chemotherapy-resistant disease, %	67
Prior auto-HCT, %	27
Bridging therapy, %	15
Median time from diagnosis to infusion (range), months	15 (2-264)

Auto-HCT, autologous hematopoietic cell transplantation; ECOG, Eastern Cooperative Oncology Group.

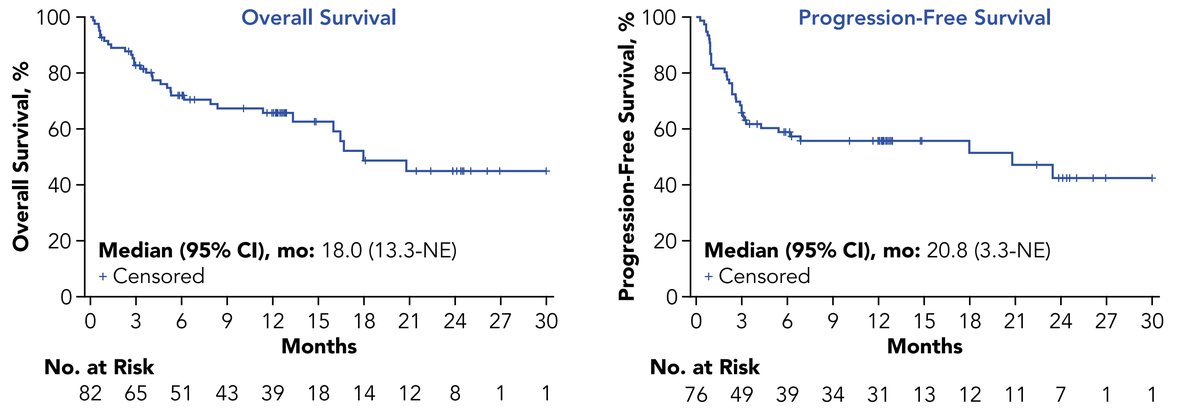
Figure 2. Objective Response and Duration of Response

CR, complete response; DOR, duration of response; NE, not evaluable; NR, not reported; ORR, objective response rate; PD, progressive disease; PR, partial response; SD, stable disease.

- At a median follow-up of 12.6 months (range, 0.2-35.5), ORR was 70% (95% CI, 58%-79%) with a CR rate of 55% (95% CI, 43%-66%) (**Figure 2**)
- Among those who achieved response, 82% (95% CI, 68%-90%) remained in response at 6 months

RESULTS *(Continued)*

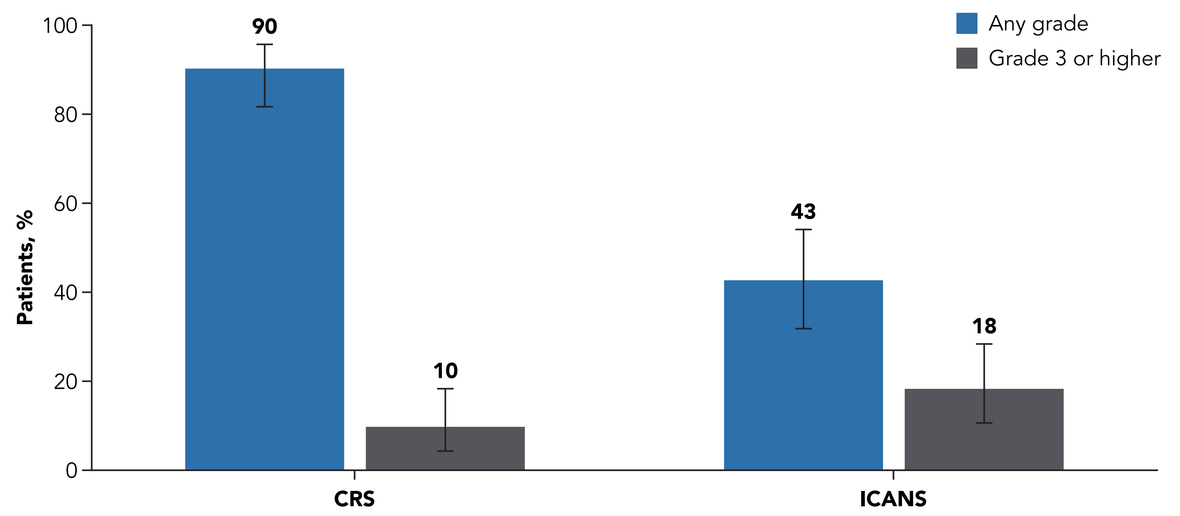
Figure 3. Overall Survival and Progression-Free Survival



NE, not evaluable; OS, overall survival; PFS, progression-free survival.

- OS and PFS at 12 months were 66% (95% CI, 54%-75%) and 56% (95% CI, 44%-66%), respectively (**Figure 3**)

Figure 4. CRS and ICANS

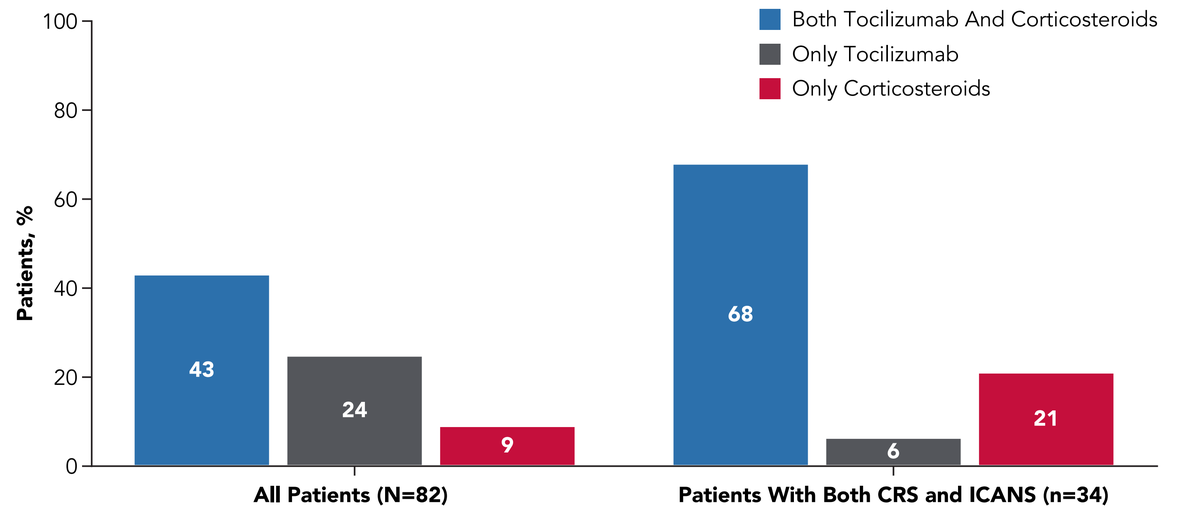


Characteristic	Patients of Asian Descent N=82
CRS	
Median time to CRS (range), days	5 (1-16)
CRS resolved by Week 3 post-onset, %	90%
ICANS	
Median time to ICANS (range), days	6 (2-22)
ICANS resolved by Week 3 post-onset, %	74%

CRS, cytokine release syndrome; ICANS, immune effector cell-associated neurotoxicity syndrome.

- Any grade and Grade ≥3 CRS occurred in 90% and 10% of patients, respectively (**Figure 4**)
- Any grade and Grade ≥3 ICANS occurred in 43% and 18% of patients, respectively (**Figure 4**)

Figure 5. Treatment for CRS and ICANS



CRS, cytokine release syndrome; ICANS, immune effector cell-associated neurotoxicity syndrome.

- Among all patients, 43% received both tocilizumab and corticosteroids, 24% received only tocilizumab, and 9% received only corticosteroids (**Figure 5**)
- Among patients who had both CRS and ICANS, 68% received both tocilizumab and corticosteroids, 6% received only tocilizumab, and 21% received only corticosteroids (**Figure 5**)

CONCLUSIONS

- This is the largest report on axi-cel use among patients of Asian descent treated in the real-world setting
- Axi-cel use among patients with Asian descent demonstrated favorable efficacy and safety outcomes, which is consistent with the findings from ZUMA-1 and the broader CIBMTR study on axi-cel use[1-3]

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DISCLOSURES

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