

**Real-world outcomes of axicabtagene ciloleucel (Axi-cel) for the treatment of large B-cell lymphoma (LBCL) by race and ethnicity.**

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**Background:** In clinical trials of CAR T-cell therapies and real-world studies published to date, there is a paucity of data on outcomes by race and ethnicity. Here, we examined outcomes by race and ethnicity among LBCL pts who received axi-cel in the real-world setting. **Methods:** A total of 1389 pts with LBCL were identified from a non-interventional post-authorization safety study with pts receiving commercial axi-cel between 10/2017 and 08/2020. Race (African American or Asian vs White) and ethnicity (Hispanic vs non-Hispanic) were self-reported by pts. Pts with rescinded consent, enrolled in trials, having prior non-HCT cellular therapy, primary CNS lymphoma, unknown comorbidity or data in query were excluded. Median follow-up was 12.7 mo. Outcomes included ORR, CR rate, DOR, PFS and OS, grade  $\geq 3$  CRS (Lee 2014 criteria) and ICANS (ASTCT consensus grade). ORR and CR were evaluated in pts with  $\geq 180$  days of follow-up. Kaplan-Meier estimates were calculated for PFS and OS. Multivariable analyses comparing race and ethnicity were conducted via logistic and Cox regression. **Results:** Among all, 1127 (81%) were White, 70 (5%) African American and 81 (6%) Asian; 152 (11%) were Hispanic including 104 White, 2 Black, and 1 Asian Hispanic. African Americans, compared to White, were younger (median age 55.5 vs 62.8 years), more likely to have pulmonary impairment (41% vs 28%) and tended to have longer time from diagnosis ( $\geq 12$  mo 71% vs 59%). Hispanic pts were younger (median age 58.5 vs 62.6 years) than non-Hispanic pts. ORR was 74% (CR 57%, 12-mo PFS and OS 48% and 63%) for White, 57% (CR 45%, 12-mo PFS and OS 36% and 62%) for African American, 67% (CR 53%, 12-mo PFS and OS 55% and 65%) for Asian and 73% (CR 55%, 12-mo PFS and OS 50% and 65%) for Hispanic pts. Grade  $\geq 3$  CRS and ICANS occurred in 7% and 18% of African American, 10% and 19% of Asian, and 8% and 27% of White pts, respectively. Hispanic pts had lower rates of grade  $\geq 3$  CRS and ICANS (4% and 15%) vs non-Hispanic (9% and 27%). African American race was associated with inferior ORR (OR 0.40; 95% CI, 0.24-0.69) and CR rate (OR 0.55; 95% CI 0.32-0.93) vs White. Asian pts had favorable DOR compared to both White (HR 0.46; 95% CI 0.24-0.87) and African American (HR 0.39; 95% CI 0.17-0.88). No statistical differences were found in OS and PFS across races, nor in any efficacy outcome between Hispanic and non-Hispanic pts. Asian (OR 0.52; 95% CI 0.29-0.96 vs White) and Hispanic pts (OR 0.51; 95% CI 0.31-0.85 vs non-Hispanic) had lower risk of grade  $\geq 3$  ICANS. **Conclusions:** Overall, axi-cel showed favorable OS, PFS and safety profile regardless of race and ethnicity in the real-world setting. No notable differences in outcomes were observed for Hispanic or Asian pts. Lower response rates in African American pts noted here warrant further investigation including any underrepresentation not explained by a lower incidence rate for DLBCL (SEER), access to care, and disease burden. Research Sponsor: Kite, a Gilead Company, Other Government Agency.